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(Filed Electronically)

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PETITION FOR STAY OF ACTION

On behalf of Schwarz Pharma, Inc. ("Schwarz"), the undersigned submit this petition under 21 C.F.R. § 10.35 to request that the Commissioner of Food and Drugs ("Commissioner") stay the potential grant of effective approval of ANDA # 77-536 for moexipril hydrochloride tablets.

A. Decision Involved

The potential grant of effective approval by FDA for ANDA # 77-536 for moexipril hydrochloride tablets, filed by Paddock Laboratories, Inc.

B. Action Requested

By this Petition for Stay, the undersigned hereby request that FDA stay any pending action to grant effective approval of ANDA # 77-536 for moexipril hydrochloride tablets unless and until the United States District Court for the District of Minnesota has ruled on outstanding FRCP Rule 59(e) Motions and has entered a judgment described in 21 U.S.C. § 355(j)(5)(B)(I)(aa), which judgment remains in effect as of the date on which the agency grants said effective approval.

2006P-0444

PSA 1

C. Statement of Grounds

1. On October 20, 2006, the United States District Court for the District of Minnesota issued a Memorandum Opinion and Order in Civ. No. 05-832 ADM/JJG deciding, on a motion for Summary Judgment, that the moexipril product of Defendant, Paddock Laboratories, Inc., covered by ANDA # 77-536, does not infringe U.S. Patent 4,743,450. *See* Attachment A.

2. On October 23, 2006, counsel for Plaintiff Schwarz Pharma, Inc. filed with the Court a letter stating Schwarz' intent to request reconsideration of the October 20, 2006 order on the grounds that, *inter alia*, the order was inappropriately based on a purported resolution of a factual dispute between the Parties to the suit. *See* Attachment B.

3. On October 26, 2006, counsel for Schwarz filed with the District Court a Motion to Alter or Amend Judgment pursuant to Federal Rule of Civil Procedure 59(e). See Attachment C. The Motion seeks withdrawal of the Court's summary judgment finding of non-infringement, based on errors of law and the improper determination of genuine issues of material fact.

4. Under the Federal Rules of Civil Procedure, the Federal Rules of Appellate Procedure, and the Local Rules of the District Court for the District of Minnesota, the effect of Schwarz' filing of a Rule 59(e) Motion on October 26, 2006, is that the Court's order of October 20, 2006 does not constitute a final judgment of the Court, and will not constitute such a judgment unless and until further order of the Court. It is well settled that a judgment is no longer final upon the filing of a timely Rule 59(e) Motion. *Miltmore Sales, Inc. v. International Rectifier, Inc.*, 412 F.3d 685, 687-88, 691 (6th Cir. 2005) (litigant's Rule 59(e) motion "destroyed the finality" of the judgment). Such a Motion tolls the time for filing an appeal and "'suspends' the finality of the initial judgment." *Federal Kemper Insur. Co. v. Rauscher,* 807 F.2d 345, 348 (3rd Cir. 1986) ("If the motion is denied, the judgment of the initial order becomes final and subject to appeal"); *see also Garrett v. United States,* 195 F.3d 1032, 1033 (8th Cir. 1999) (A Rule 59(e) Motion "suspend[s] the finality of the judgment and cause[s] the time for filing an appeal to begin to run anew from the date of the disposition of the motion"); Federal Rule of Appellate Procedure 4(a)(4)(A); *Innovative Home Health Care, Inc. v. P.T.O.T.,* 141 F3d 1284, 1286 (8th Cir. 1998) ("A case in which a timely Rule 59(e) motion has been filed lacks finality because the motion tolls the time limitation for appeal in order to provide the trial court with jurisdiction to resolve the motion. This "tolling process" encourages "both correctness and finality."

(citations omitted).). Together, Rule 59(e) of the Federal Rules of Civil Procedure and Rule 4 of the Federal Rules of Appellate Procedure ensure that the District Court "has had an opportunity to dispose of all motions that seek to amend or alter what otherwise might appear to be a final judgment." *Osterneck v. Ernst & Whinney,* 489 U.S. 169, 174 (1989).

5. Under 21 U.S.C. § 355(j)(5)(B)(I)(aa), the Court's October 20, 2006 order, and any judgment issued in accordance therewith, thus does not qualify as an effective judgment on which an effective approval can be based prior to the expiration of the 30 month period described in 21 U.S.C. § 355(j)(5)(B). Issuance of an effective approval of ANDA # 77-536 in the absence of such a judgment, which remains in effect as of the date such approval is granted, would therefore be contrary to law.

6. Schwarz will suffer irreparable harm in the event that effective approval is granted for ANDA # 77-536, in that Paddock would thereby be permitted to begin sales of its generic version of moexipril in competition with Schwarz before the District Court has completed established procedures for making and entering its final judgment on the question of whether the Paddock product infringes on listed US Patent 4,743,450.

7. Public policy supports the requested stay because it is required by statute and because it will further the deliberative process by which issues of patent infringement for generic drugs are provided by law to be litigated and finally resolved, at least at the District Court level, before a potentially infringing product is approved for marketing in less than 30 months from the date of notice of the filing.[1]

8. Neither the length of the requested stay, nor the potential result of withholding from Paddock the ability to launch its product, at risk, before the District Court issues a final judgment on whether that product infringes patent 4,743,450, will compromise the public interest in the availability of non-infringing generic drugs.

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[1] Infringing versions of generic moexipril have already been marketed in the United States due to a previous effective approval of an ANDA, based on a District Court decision of non-infringement that was subsequently overturned on appeal by the Federal Circuit after the generic product had been marketed for over six months. Schwarz Pharma, Inc. v. Warner-Lambert Co., 2004 U.S. App. LEXIS 1347 (Fed. Cir. Jan. 29, 2004). That infringing product remained on the market for more than eight additional months after the Federal Circuit reversal. Introduction to the market of the Paddock product has the potential to result in precisely the same harm again.

9. This matter is not frivolous and is being pursued by Schwarz in good faith, as evidenced by the legal and factual arguments that have been presented to the District Court in its Rule 59(e) Motion (see Attachment C hereto) regarding the validity of the District Court's October 20, 2006 Memorandum Opinion.

Respectfully submitted,

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Petition for Stay
October 26, 2006
ATTACHMENT A

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Schwarz Pharma, Inc., Schwarz Pharma AG, and Warner-Lambert Company, LLC,

Plaintiffs,

v.

Paddock Laboratories, Inc.,

Defendant.

MEMORANDUM OPINION AND ORDER
Civ. No. 05-832 ADM/JJG

Daniel L. Malone, Esq. and Brian M. Poissant, Esq., Jones Day, New York, NY; and Peter R. Forrest, Esq., Gray, Plant, Mooty, Mooty & Bennett, P.A., Minneapolis, MN, argued on behalf of Plaintiffs.

Neil F. Greenblum, Esq., Michael J. Fink, Esq., and Stephen M. Roylance, Esq., Greenblum & Bernstein, P.L.C., Reston, VA; and Beth L. Steffan, Esq., Kelly & Berens, PA, Minneapolis, MN, argued on behalf of Defendant.

I. INTRODUCTION

On August 30, 2006, oral argument before the undersigned United States District Judge was heard on Paddock Laboratories, Inc.'s ("Paddock") Motion for Summary Judgment of Noninfringment of U.S. Patent No. 4,743,450 ("the '450 patent") [Docket No. 175]. In their Complaint [Docket No. 1], Plaintiffs Schwarz Pharma, Inc. ("SPI"), Schwarz Pharma AG ("SPAG") (SPI and SPAG are collectively "Schwarz Pharma"), and Warner-Lambert Company, LLC ("Warner-Lambert") (all three collectively "Plaintiffs") aver that Paddock's planned commercial manufacture, use, and sale of Moexipril Tablets infringes the '450 patent. For the reasons stated herein, Paddock's Motion for Summary Judgment is granted.

On September 29, 2006, Schwarz Pharma filed Objections [Docket No. 208] to Magistrate Judge Jeanne J. Graham's Order [Docket No. 202] granting Paddock's Motion for

Sanctions for Violation of a Protective Order [Docket No. 163] and ordering Schwarz Pharma to pay reasonable attorney fees and costs incurred by Paddock in bringing its Motion. Schwarz Pharma's Objections are overruled, and Judge Graham's Order is adopted.

II. BACKGROUND

The '450 patent, entitled "Stabilized Compositions," discloses a pharmaceutical composition that combines Angiotensin Converting Enzyme ("ACE") inhibitors with certain stabilizers that prevent degradation, i.e., cyclization, hydrolysis, and discoloration, to create a stable medication for treating hypertension and congestive heart failure. Wiesner Decl. [Docket No. 185] Ex. 1. Warner-Lambert owns the '450 patent. Compl. ¶ 11. Warner-Lambert granted SPAG an exclusive license to manufacture and sell moexipril hydrochloride[1] products under the '450 patent, and SPAG granted an exclusive sublicense to SPI. Id. ¶ 12. SPI sells drug products containing moexipril hydrochloride under the trademark UNIVASC®. Id.

Paddock is a developer, manufacturer, and seller of generic pharmaceutical products. Countercl. [Docket No. 5] ¶ 1. Paddock submitted an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell tablets containing moexipril hydrochloride and magnesium oxide prior to the expiration of the '450 patent.[2] Id. ¶ 38; Compl. ¶¶ 13, 14. Paddock sent a Notification Letter to Plaintiffs, informing them of its ANDA and certification that its product does not infringe any claims of the '450 patent. Countercl. ¶ 40; Compl. ¶ 15. Plaintiffs allege that Paddock's filing of its ANDA

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[1] Moexipril hydrochloride is an ACE inhibitor.

[2] The '450 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluation" ("Orange Book") as covering UNIVASC® tablets.

constitutes infringement of one or more of the claims of the '450 patent. Compl. ¶ 16.

Applicants Michael Harris, Gerard Hokanson, Kuchi Murthy, Robert Reisch, and Frank Waldman filed patent application 017,962, entitled "Stabilized Compositions," with the United States Patent and Trademark Office ("PTO") on February 24, 1987. Wiesner Decl. Ex. 3 at S00005. Patent application 017,962 ultimately matured into the '450 patent. Id. The '450 patent as originally filed consisted of 19 claims. Id. at S00028-S00030. Independent claim 1 as originally filed recited:

> A pharmaceutical composition which contains:
> (a) a drug component which comprises an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration,
> (b) a suitable amount of a metal containing stabilizer to inhibit cyclization and discoloration, and
> (c) a suitable amount of a saccharide to inhibit hydrolysis.

Id. at S00028. Dependent claim 2 as originally filed recited: "The composition of Claim 1 wherein (b) contains an alkali or alkaline earth metal salt." Id. Dependent claim 3 as originally filed recited: "The composition of claim 2 wherein (b) contains an alkali or alkaline earth metal carbonate." Id. On October 1, 1987, the patent examiner rejected all 19 claims based on obviousness. Id. at S00034-S00035. The examiner specifically stated: "Claims 1-19 are rejected under 35 U.S.C. [§] 103 as being unpatentable over Veber et al. Veber et al, Examples, teach pharmaceutical compositions containing enalapril and lactose. It is the examiner's opinion that the claimed composition would be obvious in view of Veber et al." Id. at S00035.

In response, an amendment to the patent application was filed on November 23, 1987. Id. at S00037. The amendment asked the examiner to cancel claims 2 and 3, and to amend claims 1, 4, and 18. Id. The amendment essentially folded claims 2 and 3 into claim 1, altering claim 1 to recite "a suitable amount of ~~a metal containing stabilizer~~ an alkali or alkaline earth

metal carbonate . . . ." The amendment also caused originally filed claim 4 to be dependent on claim 1 instead of cancelled claim 3, and asked that in claim 18, the word "salt" be replaced with the word "carbonate." Id.[3] The amendment was supported by approximately one page of remarks, proposed by the applicants' attorney, which informed the examiner that the '450 patent is directed toward stabilized pharmaceutical compositions containing ACE inhibitors and not necessarily toward any specific use for any particular ACE inhibitor. The remarks stated in relevant part:

> Reconsideration is respectfully requested of the rejection of the claims under 35 USC 103 as allegedly being unpatentable over Veber et al. The object and teaching of the Veber patent is a new method of use for known ace inhibitors such as enalapril for treating senile macular degeneration. . . . There is no teaching or suggestion to solve any stability problems by the formulations described in Veber. In fact, there is no mention at all in the entire patent of stability or formulation problems using ACE inhibitors. In contrast, the present invention solves a severe degradation problem of ACE inhibitors which occurs on standing especially at elevated temperatures. . . . Thus, the combination of the two necessary ingredients [an alkali or alkaline earth metal carbonate and a saccharide] demonstrates the patentability of the present invention. This is especially so as now claimed by the above amendment which focuses clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide. Applicant respectfully submits that in view of the above amendment and the above remarks, the Examiner's rejection should be withdrawn.

Id. at S00037-S00038.

On December 30, 1987, a Notice of Allowability was issued, allowing claims 1, and 4-19, as amended. Id. at S00044. An examiner's amendment was also issued, adding the phrase

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[3] Originally filed claim 18 recites:

> A process for stabilizing an ACE inhibitor drug against cyclization which comprises the step of contacting the drug with:
> (a) a suitable amount of an alkali or alkaline earth-metal salt and,
> (b) one or more saccharides.

Id. at S00030.

"a suitable amount" to claim 1(a), so that it now reads "a drug component which comprises a suitable amount of an ACE inhibitor . . . ." Id. at S00045. The '450 patent in its final version, dated May 10, 1988, consists of 17 claims, with claims 1 and 16 as independent claims. Id. at S00005.

On April 18, 2006, the Court issued a Markman order, interpreting certain disputed claim terms of the '450 patent. Order [Docket No. 157]. The Court now turns to Paddock's Motion for Summary Judgment of Noninfringment.

III. DISCUSSION

A. Summary Judgment Standard of Review

Federal Rule of Civil Procedure 56(c) provides that summary judgment shall issue "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); see Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). On a motion for summary judgment, the Court views the evidence in the light most favorable to the nonmoving party. Ludwig v. Anderson, 54 F.3d 465, 470 (8th Cir. 1995). The nonmoving party may not "rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial." Krenik v. County of Le Sueur, 47 F.3d 953, 957 (8th Cir. 1995).

B. Prosecution History Estoppel

"A determination of infringement requires a two step analysis. First, the claim must be

properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused [product]." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1565 (Fed. Cir. 1997). "A claim covers an accused [product] if the [product] embodies every limitation of the claim, either literally or by an equivalent." Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993). At oral argument, Plaintiffs conceded that Paddock's product does not literally infringe the '450 patent. As a result, the '450 patent is infringed only if Paddock's product is an equivalent, meaning "there is not a substantial difference between the claimed invention and the accused product." Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1218 (Fed. Cir. 1995).

"[P]rosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995). Prosecution history estoppel includes both amendment-based estoppel and argument-based estoppel, and is a question of law for the court. Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc., 347 F.3d 1314, 1324 (Fed. Cir. 2003); Ranbaxy Pharms., Inc. v. Apotex, Inc., 350 F.3d 1235, 1240 (Fed. Cir. 2003). "[T]he resolution of factual issues underlying a legal question may properly be decided by the court." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1368 n.3 (Fed. Cir. 2003) ("Festo II").

1. Argument-Based Estoppel

"To invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter." Deering Precision Instruments, 347 F.3d at 1326. "Unmistakable assertions made by the applicant to the PTO in support of patentability, whether

or not required to secure allowance of the claim, may operate to preclude the patentee from asserting equivalency." Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1252 (Fed. Cir. 2000). The prosecution history must be examined from an objective standpoint, and the proper inquiry is "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Id. Additionally,

> [T]estimony as to what a reasonable competitor would conclude from the prosecution history cannot create a genuine issue of material fact so as to bar summary judgment. Such testimony is only a tool, which the judge can use at . . . her discretion, to aid in the legal determination of prosecution history estoppel.

Id. at 1254.

Paddock argues that argument-based prosecution history estoppel bars Plaintiffs from asserting infringement under the doctrine of equivalents. Paddock points to arguments made before the PTO in which the applicants' attorney stated that an alkali or alkaline earth metal carbonate is a necessary ingredient and the claims had been amended to clearly focus on the use of an alkali or alkaline earth metal carbonate. Paddock cites three Federal Circuit cases in support of its argument. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241 (Fed. Cir. 2000); Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373 (Fed. Cir. 1999); Tex. Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165 (Fed. Cir. 1993).

All three cases cited by Paddock are distinguishable from the instant case. Although the patentees in those cases argued to the PTO that a particular aspect of their invention was "critical," "unique," "superior," or "key," they also argued that a potential equivalent to the particular aspect was "not . . . desired," "unworkable," "not . . . easily and readily manufacturable," or a "disadvantage." Bayer, 212 F.3d at 1252-54; Pharmacia, 170 F.3d at 1377-78; Tex. Instruments, 988 F.2d at 1174-75. For example, in Pharmacia, the patentee's

argument that "spray-dried lactose is a critical feature of the present invention" and "lactose which is not spray-dried does not yield a formulation which is easily and readily manufacturable" led the court to conclude that the patentee had surrendered equivalents to its invention that did not contain spray-dried lactose. 170 F.3d at 1377-78. By contrast, in the present case, although the applicants' attorney argued to the PTO that an alkali or alkaline earth metal carbonate was one of the "two necessary ingredients [that] demonstrates the patentability of the present invention" and that the amendment to independent claim 1 was made to "focus[] clearly on the use of an alkali or alkaline earth metal carbonate," he made no arguments with respect to potential equivalents to an alkali or alkaline earth metal carbonate and whether or not they would be less desirable or unworkable. See Wiesner Decl. at S00037-S00038. For example, there is no clear disavowal of magnesium oxide. Furthermore, the purpose of the remarks appears to be directed toward emphasizing the patentability of the '450 patent over the Veber patent because the '450 patent focuses on stabilizing ACE inhibitors, while the Veber patent focuses on using known ACE inhibitors to treat senile macular degeneration. As a result, from the perspective of a reasonable competitor, the arguments before the PTO do not evince a clear and unmistakable surrender of subject matter and argument-based prosecution history estoppel does not apply.

2. Amendment-Based Estoppel

For amendment-based estoppel, "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002) ("Festo I"). Once a court concludes that "a narrowing amendment has been made for a substantial reason related to patentability," a

presumption applies "that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation." Festo II, 344 F.3d at 1367. The patentee may rebut the presumption of total surrender by demonstrating that (1) the alleged equivalent would have been unforeseeable at the time of the narrowing amendment, (2) the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question, or (3) there was "some other reason" suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent. Id. at 1368, citing Festo I, 535 U.S. at 740-41.

a. Presumption of Total Surrender

Paddock argues that the amendment made to the '450 patent was a narrowing amendment made to obtain allowance of the patent after the examiner rejected all of the claims as unpatentable over the prior art. Paddock further argues that as a result, Plaintiffs are deemed to have surrendered coverage for metal containing stabilizers and alkali and alkaline earth metal salts other than alkali and alkaline earth metal carbonates. Paddock points to the arguments made to the examiner as further evidence that the scope of the claims was narrowed, thus giving rise to prosecution history estoppel and an inability to pursue infringement under the doctrine of equivalents.

Plaintiffs respond that the amendment did not presumptively surrender magnesium oxide because the claims of the '450 patent as originally drafted did not encompass magnesium oxide. Accordingly, prosecution history estoppel is inapplicable. Plaintiffs point to the specification to show that the term "metal containing stabilizer" found in original claim 1 means an alkali or alkaline earth metal carbonate, borate, or silicate, and does not include magnesium oxide.

Plaintiffs' argument is not persuasive. The Stabilizer(s) section of the specification states in relevant part:

> The alkaline stabilizers of the invention include the inorganic salts of metals of Groups I and II of the Periodic Table. Thus, salts of alkali and alkaline earth metals are operable. Magnesium, calcium, and sodium are preferred. Magnesium is most preferred. The anionic portion of the salt employe[d] may be any which does not deleteriously affect the stability of the overall formulation. Thus, borates, silicates, and carbonates are contemplated. Carbonates are preferred. Mixtures are operable.

Wiesner Decl. Ex. 1 ('450 patent) at col. 3:30-39. It appears that while borates, silicates, and carbonates are contemplated, they are not exclusive. See Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (cautioning courts not to import limitations from the specification into the claims). The specification clearly states that "[t]he anionic portion of the salt employe[d] may be *any* which does not deleteriously affect the stability of the overall formulation. '450 patent at col. 3:35-37 (emphasis added). Here, Plaintiffs' expert conceded that the ordinary and accustomed meaning of an alkali or alkaline earth metal salt would encompass magnesium oxide, and that magnesium oxide is a compound that has anionic portion that does not deleteriously affect the stability of an ACE inhibitor formulation. Pejic Decl. [Docket No. 178] Ex. 2 (Williams Dep.) at 51-52, 98. Thus the claims of the '450 patent as originally drafted encompassed magnesium oxide.

Also, Paddock's argument that the amendment made to the '450 patent was a narrowing amendment is persuasive. The amendment resulted in original independent claim 1 incorporating the limitations of original dependent claims 2 and 3. Plaintiffs' expert agreed that the amendment was a narrowing amendment made to obtain allowance of the patent. Williams Dep. at 82-84. In addition, although the majority of the applicants' attorney's remarks appear to be directed toward demonstrating to the examiner how the '450 patent is distinguishable from

and patentable over the Veber patent—the Veber patent is directed toward a particular use for ACE inhibitors and the '450 patent is directed toward stabilizing ACE inhibitors—the applicants' attorney specifically states that the amendment is in response to the October 1, 1987 Office Action, in which the examiner rejected the '450 patent for obviousness over the prior art. The remarks also point out that "the combination of the two necessary ingredients demonstrates the patentability of the present invention. This is especially so as now claimed by the above amendment which focuses clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide." Wiesner Decl. Ex. 3 at S00038. As a result, the amendment was a narrowing amendment made for a substantial reason related to patentability, and the presumption that the patentee surrendered all territory between the original claim limitation and the amended claim limitation applies.

b. Rebutting the Presumption

i. Foreseeability

The foreseeability test is an "objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment." Festo II, 344 F.3d at 1369. The Federal Circuit has stated that "if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment." Id. The foreseeability analysis, while ultimately a matter of law, involves underlying factual issues for which the Court can consider extrinsic evidence including expert testimony. Id.

Paddock argues that Plaintiffs can not rebut the presumption of total surrender because magnesium oxide was known as a stabilizer in the art of pharmaceutical formulation—the field

of the invention of the '450 patent—at the time of the amendment, and therefore was foreseeable as an equivalent. Paddock relies on Glaxo Wellcome Inc. v. Impax Laboratories Inc., 356 F.3d 1348 (Fed. Cir. 2004). In Glaxo, the owner of a patent for a sustained release formulation of the drug bupropion hydrochloride combined with hydroxypropyl methylcellulose ("HPMC"), sued a generic drug manufacturer for infringement based on its ANDA for a sustained release drug combining bupropion hydrochloride with hydroxypropyl cellulose ("HPC"). 356 F.3d at 1350-51. The Federal Circuit upheld the district court's summary judgment determination of noninfringement on the basis of prosecution history estoppel. Id. The court determined that Glaxo had made a narrowing amendment, surrendering other controlled sustained release agents known to act as equivalents for HPMC, and that HPC was a foreseeable sustained release agent at the time of the amendment. Id. at 1352, 1355-56. Although the record showed that at the time of the amendment, only HPMC had been tested specifically with bupropion hydrochloride to achieve sustained release, HPC was known as a sustained release hydrogel-forming polymer in the art of pharmaceutical formulation, as evidenced by the Handbook of Pharmaceutical Excipients, other patents, and an Information Disclosure Statement submitted by Glaxo to the PTO. Id. at 1355-56.

In support of its argument that magnesium oxide was a known stabilizer in the field of pharmaceutical formulation at the time of the amendment on November 11, 1987, Paddock cites to prior art references teaching the use of magnesium oxide as a stabilizer, the knowledge of the inventors of the '450 patent, and the testimony of experts. Paddock avers that the inventors of the '450 patent conducted stability experiments combining magnesium oxide with an ACE inhibitor prior to November 1987. Pejic Decl. Ex. 31-32. Paddock also argues two Japanese

patents, fourteen United States patents, and one Great Britain patent reference magnesium oxide as a stabilizer in the field of pharmaceutical formulation. Pejic Decl. Exs. 12-28.

Plaintiffs respond that Glaxo is distinguishable from the instant case because in Glaxo, the parties did not dispute that HPMC and HPC were known equivalents at the time of the amendment. In this case, Plaintiffs aver two experts have opined that magnesium oxide and magnesium carbonate were not known substitutes or recognized as interchangeable, at the time of the amendment. See Williams Decl. [Docket No. 186] at 6-18; Gokel Decl. [Docket No. 184] at 7-13. But see Dash Decl. [Docket No. 179] at 19-29. Plaintiffs also argue that Paddock's expert witness, Dr. Dash, presents a logically inconsistent opinion that while magnesium oxide was foreseeable at the time of the amendment, it is not an equivalent to magnesium carbonate today. Further, Plaintiffs argue that Paddock's references to other patents are not instructive, as none of the other patents concern ACE inhibitors, and none of the other patents mention cyclization. Plaintiffs also argue that what the '450 patent inventors understood is irrelevant to what a person of ordinary skill in the art understood. Further, the inventors' experiments do not support Paddock's contentions.

The Court finds that an analysis of the entire record, including Paddock's prior art references and the testimony of the experts, reveals that magnesium oxide was a known stabilizer in the field of pharmaceutical formulation at the time of the amendment of the '450 patent. In Glaxo, the court found that although only HPMC had been tested specifically with bupropion hydrochloride to achieve sustained release, HPC was known as a sustained release hydrogel-forming polymer in the art of pharmaceutical formulation, and as a result, was foreseeable as an equivalent to HPMC. Id. at 1355-56. Similarly, in this case, although Paddock's prior art

references do not concern ACE inhibitors, they still show that magnesium oxide was known as a stabilizer in the field of pharmaceutical formulation, and as a result, it was foreseeable to one of ordinary skill in the art as a potential equivalent to magnesium carbonate at the time of the amendment.[4] Because magnesium oxide was foreseeable, the Festo presumption is not rebutted and summary judgment on the basis of prosecution history estoppel is granted.

ii. Tangential Relation

The "tangential relation" test requires a patentee to establish that the objectively apparent reason for the narrowing amendment, discernible from the prosecution history record, was not directly relevant to the alleged equivalent. Festo II, 344 F.3d at 1369. In its opening memorandum, Paddock argues that Plaintiffs can not satisfy the "tangential relation" test because the narrowing amendment was made to overcome the examiner's prior art rejection, as is evident from the applicants' attorney's argument to the examiner that the patentability of the invention is apparent "as now claimed by the above amendment which focuses clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide." Wiesner Decl. Ex. 3 at S00038. Plaintiffs respond that they can satisfy the "tangential relation" test because the amendment had nothing to do with the examiner's rejection, and the prosecution history shows that the applicants asked the examiner to reconsider his obviousness rejection since the Veber patent concerns the use of ACE inhibitors in the treatment of eye disease and the '450 patent

[4] The Court finds the arguments concerning what the inventors knew or did not know about magnesium oxide as a stabilizer to be irrelevant to determining what a person of ordinary skill in the art at the time of the amendment knew. See Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985). However, it is of interest that inventor Frank Waldman conducted stability experiments using magnesium oxide, Quinapril (an ACE inhibitor), and lactose on July 15, 1987, prior to the amendment of the '450 patent. Pejic Decl. Exs. 11 (Waldman Dep.) at 40-42, 31 at 55.

concerns stabilizing ACE inhibitor formulations. In its reply memorandum, Paddock states that even if the amendment was not made to overcome the examiner's rejection, Plaintiffs have still not set forth a reason for the narrowing amendment and therefore can not argue that the rationale behind the amendment bore no more than a tangential relationship to magnesium oxide. See Festo II, 344 F.3d at 1371-72.

As is discussed above, the amendment was a narrowing amendment made to obtain allowance of the patent. The applicants intended to make it clear to the examiner that the '450 patent was patentable over the Veber patent—even though the '450 patent disclosed a pharmaceutical composition that contained an ACE inhibitor and a saccharide, as did the Veber patent, it also disclosed some type of metal containing stabilizer and was directed specifically toward stabilizing all types of ACE inhibitors, while the Veber patent was only directed toward using ACE inhibitors to treat senile macular degeneration. Although there is no evidence that the applicants had magnesium oxide in mind when they made the amendment, the fact remains that the amendment was a narrowing amendment which had the effect of potentially surrendering all territory between the original claim limitation and the amended claim limitation, including magnesium oxide. As a result, the Plaintiffs can not establish that the objectively apparent reason for the narrowing amendment was not directly relevant to the alleged equivalent. Also, even if the amendment was not made to overcome the examiner's prior art rejection, the Plaintiffs have not provided an alternative reason for the amendment, as they are required to do. See Festo II, 344 F.3d at 1371-72. Plaintiffs can not rebut the Festo presumption by satisfying the tangential relation test.

C. Objections to Magistrate Judge Jeanne J. Graham's Order

On September 15, 2006, Magistrate Judge Jeanne J. Graham issued an Order granting Paddock's Motion for Sanctions for Violation of a Protective Order and ordering Schwarz Pharma to pay reasonable attorney fees and costs incurred by Paddock in bringing its Motion. Schwarz Pharma has filed Objections to Judge Graham's Order, arguing that their violation of the protective order was merely inadvertent or technical and Paddock has suffered no harm. As a result, they argue Schwarz Pharma should not have to pay attorney fees and costs. Paddock responds that it was harmed by Schwarz Pharma's violation of the protective order, and as a remedy, the Court should strike the portions of Plaintiffs' expert reports that rely on PharmaForm's testing and preclude Plaintiffs from introducing any testimony or evidence relating to the tests.

In reviewing objections to a Magistrate Judge's order, the District Judge "shall consider such objections and shall modify or set aside any portion of the Magistrate Judge's order found to be clearly erroneous or contrary to law." D. Minn. LR 72.2(a); see also 28 U.S.C. § 636(b)(1)(A). "Civil contempt may be employed either to coerce the defendant into compliance with a court order or to compensate the complainant for losses sustained, or both." Chicago Truck Drivers v. Brotherhood Labor Leasing, 207 F.3d 500, 504 (8th Cir. 2000). In this case, as Judge Graham found, Schwarz Pharma concedes it violated the protective order, and Paddock's Motion has merit. As a result, an award of Paddock's reasonable attorney fees and costs in connection with bringing the Motion is an appropriate remedy, and Judge Graham's holding was not clearly erroneous or contrary to law. See Kehm v. Proctor & Gamble Mfg. Co., 724 F.3d 630, 630-31 (8th Cir. 1984) (holding award of attorney fees in connection with contempt

proceedings appropriate where party disclosed documents subject to a protective order). Further, in light of the Court's summary judgment ruling, Paddock's request that portions of Plaintiffs' expert testimony and scientific testing be stricken is moot. Schwarz Pharma's Objections are overruled and Judge Graham's Order is adopted.

IV. CONCLUSION

Based upon the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Paddock Laboratories, Inc.'s Motion for Summary Judgment [Docket No. 175] is **GRANTED**;

2. Schwarz Pharma's Objections [Docket No. 208] are **OVERRULED**; and

3. Magistrate Judge Jeanne J. Graham's Order [Docket No. 202] is **ADOPTED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

BY THE COURT:

s/Ann D. Montgomery
ANN D. MONTGOMERY
U.S. DISTRICT JUDGE

Dated: October 20, 2006.

Petition for Stay
October 26, 2006
ATTACHMENT B

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Hon. Ann D. Montgomery, U.S.D.J.
United States District Court, District of Minnesota
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Re: Schwarz Pharma, Inc. *et. al.* v. Paddock Labs, Inc.
Civ. Act. No. 05-832 (ADM/JJG)

Dear Judge Montgomery:

We write to inform the Court that Schwarz Pharma intends to file within the next few days a motion to reconsider this Court's grant of summary judgment to Paddock, pursuant to Fed. R. Civ. P. 59(e).[1] This renders this Court's entry of judgment not final. *See Innovative Home Health Care, Inc. v. P.T.O.T.*, 141 F.3d 1284, 1286 (8th Cir.1998) ("A case in which a timely Rule 59(e) motion has been filed lacks finality. . . ").

This Court granted Paddock summary judgment stating: "Although Paddock's prior art references do not concern ACE inhibitors, they still show that magnesium oxide was a known stabilizer in the field of pharmaceutical formulations, and as a result, it was foreseeable . . . as a potential equivalent to magnesium carbonate at the time of amendment." With all due respect, this reasoning constitutes reversible error. First, Schwarz Pharma very much disputed whether magnesium oxide was a known stabilizer in the general field of pharmaceutical formulations. *See, e.g.,* Wiesner Decl. Ex. 11(describing it as a diluent). Schwarz Pharma was entitled to have its evidence, and all reasonable inferences from its evidence, credited. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.")[2]

Second, the Court wrongly conflated what are two separate factual inquires. The Court concluded that if Paddock's references disclose magnesium oxide as some sort of stabilizer, then "as a result" magnesium oxide was a foreseeable equivalent in the claimed invention. This conclusion is legally and factually erroneous. Even if an alleged equivalent is disclosed in the prior art, foreseeability requires a separate factual showing that the ordinarily-skilled artisan would have recognized that alleged equivalent and the claim element at issue to be interchangeable. For example, in *Festo*, 344 F.3d at 1359, the prior art disclosed the alleged

[1] Schwarz Pharma files this letter given the uncertainty of the applicability of LR. 7.1. *Cf.* L.R. 7.1 (requiring leave for reconsideration) *with DuBose v. Kelly*, 187 F.3d 999, 1002 (8th Cir. 1999) (construing 7.1 as inapplicable to post-judgment motions).

[2] At the summary judgment hearing, the Court questioned whether different or additional evidence would be presented at trial. Tr. 34:23-36:1. Schwarz Pharma respectfully submits that this is legally irrelevant. "[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, at 249-50. With all due respect to the Court, its opinion never discusses whether there is a genuine issue of fact for trial. This is error.

equivalent, an aluminum sleeve. Nonetheless, the Court remanded for a trial:

> Although it seems unlikely that an aluminum sleeve would have been unforeseeable, as it was made of a commonly available metal, Festo argues that one skilled in the art at the time of the "magnetizable" amendment would not have foreseen the interchangeability of an aluminum alloy sleeve and a magnetizable alloy sleeve in Stoll's small gap design involving rare earth magnets. **Factual issues thus exist as to whether an ordinarily skilled artisan would have thought an aluminum sleeve to be an unforeseeable equivalent of a magnetizable sleeve in the context of the invention.**

Similarly, in *Glaxo*, the Court upheld the grant of summary judgment not merely because the alleged equivalent had been disclosed in the prior art, but also because the record *lacked any evidence whatsoever* that the alleged equivalent would not have been considered interchangeable with the claim element in dispute, *i.e.*, a suitable sustained release agent. *Glaxo*, at 1356 ("This Court has scoured the record in vain for any evidence of a verifiable scientific reason that *Glaxo* would not have considered HPC a suitable sustained release agent for bupropion, [the active pharmaceutical ingredient in the claimed formulations].") Thus, under *Festo* and *Glaxo*, even if the alleged equivalent is disclosed in the prior art, foreseeability involves a separate factual inquiry as to whether, at the time of amendment, a person of ordinary skill in the art would have recognized that alleged equivalent to be interchangeable with the claim element in dispute given the context of the invention. This Court erred in concluding that foreseeability necessarily results from an alleged equivalent simply being disclosed in the prior art.

Additionally, here, this Court overlooked Schwarz Pharma's evidence establishing that, despite the disclosures of Paddock's references, a person of ordinary skill in the art, at the time of amendment, would *not* have recognized magnesium oxide to be interchangeable with an "alkali or alkaline earth metal carbonate," the claim element in dispute. For example,

> [E]ven if magnesium oxide could perform a stabilizing function in amfenac [the compound at issue in a Paddock reference], the structure of amfenac is too different from the structures of ACE inhibitors. . . to enable one skilled in the art to draw any meaningful conclusions from this regarding what role magnesium oxide might play in an ACE inhibitor formulation. Gokel, at ¶ 26. *See also* Williams, at ¶¶ 26-29.

> While amfenac's stability is based on the presence of divalent metals, the stability of the ACE inhibitors disclosed in the '450 patent cannot be based on this, since the claimed stabilizers do not all contain divalent metals. <u>This indicates to me that magnesium oxide would not have been recognized to be interchangeable with the "alkali or alkaline earth metal carbonate" of the claimed invention by one of ordinary skill in the art on November 11, 1987.</u> Gokel, at ¶ 28; *see also* Williams, at ¶ 29.

This and Schwarz Pharma's other similar evidence must be credited on summary judgment. Thus, Schwarz Pharma supplied the very evidence found critical in *Glaxo* and *Festo*, but this Court did not credit that evidence on summary judgment. This is error.

Respectfully submitted,

/s/

Brian M. Poissant

cc: Michael Fink, Esq.

Petition for Stay
October 26, 2006
ATTACHMENT C

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

SCHWARZ PHARMA, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 05-832 ADM (JJG)
	)	
PADDOCK LABORATORIES, INC.,	)	
	)	
Defendant.	)	
	)	

SCHWARZ PHARMA'S MEMORANDUM IN SUPPORT OF ITS MOTION TO ALTER OR AMEND JUDGMENT PURSUANT TO FED. R. CIV. P. 59(e)

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Dated: October 26, 2006

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Schwarz Pharma, Inc. and Schwarz Pharma AG ("Schwarz Pharma") respectfully submit this memorandum in support of their motion pursuant to Fed. R. Civ. P. 59(e) to alter or amend this Court's judgment in favor of Paddock Laboratories, Inc. ("Paddock"). For the reasons discussed below, this Court should vacate that judgment.[1]

I. INTRODUCTION

This Court clearly erred in granting Paddock summary judgment of non-infringement. As explained herein, the Court's analysis of the foreseeability inquiry is based on a misreading of the Federal Circuit case the Court relied upon, *Glaxo Wellcome Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348 (Fed. Cir. 2004). This misreading resulted in the Court failing to appreciate that there are genuinely disputed issues of material fact that require trial. Moreover, the Court additionally erred in deciding other genuinely disputed factual issues on summary judgment. Accordingly, the decision is erroneous and should be vacated.

II. ARGUMENT

A. Legal Standard Under Rule 59(e)

A motion to alter or amend a judgment pursuant to Fed. R. Civ. P. 59(e) serves the purpose of "correcting manifest errors of law or fact or to present newly discovered evidence." *Innovative Home Health Care, Inc. v. P.T.O.T. Assocs. of the Black Hills*, 141 F.3d 1284, 1286 (8th Cir.1998). "Although the words 'alter or amend' imply something

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[1] Local Rule 7.1's requirement that a party seek leave to file for reconsideration is inapplicable to motions under Fed. R. Civ. P. 59(e). *See DuBose v. Kelly*, 187 F.3d 999, 1002 (8th Cir. 1999); *Gas Aggregation Services, Inc. v. Howard Avista Energy, LLC*, 2005 WL 4257970, *1 (D.Minn. 2005).

less than 'set aside,' a court may use Rule 59(e) to set aside the entire judgment." *Sanders v. Clemco Industries*, 862 F.2d 161, 169 (8th Cir. 1988) (*citing A.D. Weiss Lithograph Co. v. Illinois Adhesive Prods. Co.*, 705 F.2d 249, 250 (7th Cir. 1983)). Here, as discussed below, this Court's grant of summary judgment is erroneous and should be vacated. [2]

B. This Court's Conclusion That Magnesium Oxide Was A Foreseeable Equivalent "As a Result" of Its Disclosure In Paddock's Prior Art References Is Legally and Factually Erroneous

1. The Federal Circuit Has Held That The Disclosure Of An Alleged Equivalent In the Prior Art Does Not Necessarily Render That Equivalent Foreseeable

To find an alleged equivalent foreseeable, the evidence must show that, at the time of amendment, the alleged equivalent would have been recognized by one of ordinary skill in the art as interchangeable with the claim element in dispute given the context of the invention. **This is true even if that alleged equivalent was found in the prior art at the time of amendment.** For example, in *Festo,* the alleged equivalent was an aluminum sleeve. No one disputed that such a sleeve was in the prior art. After all, aluminum was a commonly available metal. Despite the presence of this alleged equivalent in the prior art, the Federal Circuit remanded the *Festo* case to the district court on the issue of foreseeability. It did so because factual issues existed regarding the interchangeability of that equivalent and the claim element in dispute:

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[2] Where a Rule 59(e) motion has been filed, the underlying judgment "lacks finality." *Innovative Home,* 141 F.3d at 1286; *see also Garrett v. U.S.*, 195 F.3d 1032, 1033 (8th Cir. 1999) ([Rule 59(e)] motions suspend the finality of the judgment. . .").

> Although it seems unlikely that an aluminum sleeve would have been unforeseeable, as it was made of a commonly available metal, **Festo argues that one skilled in the art at the time of the "magnetizable" amendment would not have foreseen the *interchangeability* of an aluminum alloy sleeve and a magnetizable alloy sleeve in Stoll's small gap design involving rare earth magnets. Factual issues thus exist as to whether an ordinarily skilled artisan would have thought an aluminum sleeve to be an unforeseeable equivalent of a magnetizable sleeve in the context of the invention.** Accordingly, we remand to the district court on the question of unforeseeability to allow the parties to introduce evidence on this issue.

Festo, 344 F.3d 1359, 1371 (Fed. Cir. 2003)(emphasis added). Thus, *Festo* holds that the foreseeability inquiry does not end merely because the alleged equivalent is disclosed in the prior art. Instead, the inquiry moves on to the question of whether one of ordinary skill in the art would have understood that equivalent to be interchangeable with the claim element in dispute given the context of the invention. This is a factual issue – one that in *Festo* required a trial in the district court on remand.

Similarly, in *Smithkline Beecham Corp v. Excel Pharmaceuticals, Inc.,* 356 F.3d 1357 (Fed. Cir. 2004), a companion case to *Glaxo*, the Federal Circuit vacated a grant of summary judgment. The Court's instructions to the district court on remand are instructive. Notably, the Federal Circuit did not direct the district court to merely consider the issue of whether the alleged equivalent PVA (polyvinyl alcohol) was known in the art of pharmaceutical formulations as a sustained release agent. Instead, it directed the district court to ascertain whether the disclosure of PVA in the prior art would have led one of ordinary skill in the art to have foreseen the substitution of the alleged equivalent for the claim element in dispute at the time of amendment:

> On remand, the trial court may inquire into the specific use of PVA in the prior art of sustained drug release compositions to ascertain whether artisans of ordinary skill in this art would have foreseen the potential substitution of PVA for HPMC at the time the '798 patent claims were amended.

Smithkline, 356 F.3d at 1365. Thus, under *Festo* and *Smithkline*, even if the alleged equivalent is disclosed in the prior art, a proper foreseeability analysis requires a separate and additional factual inquiry as to whether, at the time of amendment, a person of ordinary skill in the art would have recognized that alleged equivalent to be interchangeable with the claim element in dispute given the context of the invention. Put differently, the disclosure of an alleged equivalent in the prior art is necessary for a finding of foreseeability, but it does not end the inquiry.

2. ***Glaxo* Is Not To The Contrary**

This Court's summary judgment decision runs afoul of the above legal principles. Specifically, in granting summary judgment, the Court never addressed the issue of whether a person of ordinary skill in the art would have recognized magnesium oxide as interchangeable with the "alkali or alkaline earth metal carbonate" of the claimed invention given the context of the invention. The Court failed to do so because it overlooked a key portion of the Federal Circuit's opinion in *Glaxo*. Consequently, it misread that case and arrived at a conclusion that is contrary to the above cases as a matter of law, and contrary to the record in this case as a matter of fact. This Court's entire discussion of its reasoning regarding foreseeability is the following two sentences:

> In *Glaxo*, the Court found that although only HPMC had been tested specifically with bupropion hydrochloride to achieve sustained release, HPC was known as a sustained release hydrogel-forming polymer in the art

> of pharmaceutical formulation, and as a result, was foreseeable as an equivalent to HPMC. (*Id.* at 1355-56). Similarly, in this case, although Paddock's prior art references do not concern ACE inhibitors, they still show that magnesium oxide was a known stabilizer in the field of pharmaceutical formulations, and as a result, it was foreseeable . . . as a potential equivalent to magnesium carbonate at the time of amendment.

(Opinion, at 13-14). The first sentence quoted describes the Court's reading of *Glaxo*. In sentence two, the Court then compares this case to *Glaxo* by analogy. But, with all due respect to the Court, the first sentence describing *Glaxo* is dead wrong. The Federal Circuit in *Glaxo* never concluded that HPC was a foreseeable equivalent solely "as a result" of its disclosure in the prior art as a sustained release agent. The Federal Circuit unmistakably undertook the second step of the foreseeability inquiry addressed above. It considered whether the record contained evidence showing that, at the time of amendment, a person of ordinary skill in the art would have recognized HPC as interchangeable with HPMC in the claimed invention:

> [T]his court has scoured the record in vain for any evidence of a verifiable scientific reason that *Glaxo* would not have considered HPC a suitable sustained release agent for bupropion. As the district court also observed, the record shows only that "anyone skilled in the art [at the relevant time] would have known that HPC and HPMC were substantially equivalent."

Glaxo, 356 F.3d at 1356. Thus, the Court concluded that HPC was a foreseeable equivalent not merely because it had been disclosed in the prior art as a sustained release agent, but also because the record contained no evidence whatsoever that raised any question as to whether, at the time of amendment, HPC and HPMC would have been recognized as interchangeable given the context of the invention. The record showed "only" that "anyone skilled in the art [at the relevant time] would have known that HPC

and HPMC were substantially equivalent." Indeed, the record in that case contained a clear and unequivocal admission by the patentee of known interchangeability at the time of amendment. *Glaxo Wellcome, Inc. v. Impax Labs, Inc.* 220 F.Supp.2d 1089, 1095 (N.D. Cal 2002) ("Plaintiff [the patentee] conceded that the two chemicals [HPC and HPMC] have been known substitutes for a lot of years.") Accordingly, under *Glaxo*, recognized interchangeability did not necessary follow "as a result" of the disclosure of the alleged equivalent in the prior art. It was a separate and additional evidentiary question. One that in that case was entirely one-sided, thus, warranting summary judgment.[3]

Accordingly, properly read, *Glaxo* is not contrary to either *Festo* or *Smithkline.* Like those cases, it stands for the proposition that even if an alleged equivalent is disclosed in the prior art, a finding of foreseeability nonetheless requires a separate and additional factual showing that, at the time of amendment, the alleged equivalent would have been recognized by one of ordinary skill in the art as interchangeable with the claim

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[3] That the Federal Circuit affirmed the grant of summary judgment in *Glaxo* is not surprising given that the record included: (1) an admission that HPC, the alleged equivalent, was disclosed in the prior art as a sustained release agent; (2) an admission that HPC and HPMC, the claim element at issue, were in fact interchangeable; and (3) an admission that they were recognized by those of skill in the art to have been interchangeable in the context of the claimed invention at the time of amendment. Notably, in the companion opinion to *Glaxo* issued the very same day, where the latter admission was absent, the Federal Circuit vacated a grant of summary judgment and remanded for trial. *Smithkline,* 356 F.3d at 1365. Here, of course, the first and third admissions above are not only absent, the evidentiary points at issue are disputed between the parties. Moreover, as to the second admission above, here, Paddock's expert disputes whether the alleged equivalent and the disputed claim element are interchangeable. Thus, the record here is a far cry from the record in *Glaxo* when that case is properly understood.

element in dispute given the context of the invention. This Court's reading of *Glaxo* as being to the contrary is wrong.

3. The Court's Failed To Credit Schwarz Pharma's Evidence Regarding Non-Recognition of Interchangeability

Based on its misreading of *Glaxo*, this Court's consideration of foreseeability in the present case by analogy to *Glaxo* is also wrong. Specifically, this Court wrongly concluded that magnesium oxide was a foreseeable equivalent "as a result" of its (alleged) disclosure in Paddock's prior art references as a stabilizer. As shown above, under *Festo, Glaxo* and *Smithkline*, even if Paddock's references disclose magnesium oxide as a stabilizer of some sort, a proper foreseeability analysis requires a separate and additional factual inquiry as to whether a person of ordinary skill in the art, at the time of amendment, would have understood that equivalent to have been interchangeable with an "alkali or alkaline earth metal carbonate" in the claimed invention given the context of the invention.[4] If one "scours" the record here, Schwarz Pharma submits that the only credible evidence to be found is that, at the time of amendment, a person of ordinary skill in the art would *not* have recognized magnesium oxide to be interchangeable with an "alkali or alkaline earth metal carbonate" in the claimed invention, despite the disclosures

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[4] The Court stated in its opinion that the relevant issue is whether magnesium oxide was a foreseeable equivalent to "magnesium carbonate." Opinion at 14. This is wrong. The claim element at issue is "alkali or alkaline earth metal carbonate." Thus, the interchangeability issues focuses on that element and the alleged equivalent. This distinction is highly pertinent to properly appreciating the disclosure of one of Paddock's references, which, as Schwarz Pharma's technical experts explained, teaches that magnesium oxide would not be interchangeable with the element "alkali or alkaline earth metal carbonate" of the claimed invention. (*See* Gokel Decl. ¶ 35; Williams Decl. ¶ 50).

of Paddock's references. Thus, at a minimum, there are clearly genuine issues of material fact that are disputed. Consequently, there are issues of fact regarding interchangeability that require a trial.

For example, Schwarz Pharma submitted evidence from its technical experts, Dr. Gokel and Dr. Williams, establishing that magnesium oxide would not have been recognized as interchangeable with the "alkali or alkaline earth metal carbonate" of the claimed invention despite the disclosures of Paddock's references. Specifically, they stated, in part, as follows:

> * In my opinion, even if magnesium oxide could perform a stabilizing function in amfenac, **the structure of amfenac [the active pharmaceutical ingredient disclosed in one of Paddock's references] is too different from the structures of ACE inhibitors, including quinapril and moexipril, to enable one skilled in the art to draw any meaningful conclusions from this regarding what role magnesium oxide might play in an ACE inhibitor formulation [*i.e.*, the claimed invention]**. (Gokel Decl. ¶ 26; see also Williams Decl. ¶ 30).
>
> * The "stabilization effect" taught by JP '710 [one of Paddock's prior references] is not found in amfenac formulations containing alkali metals [*i.e.*, potassium carbonate, kalium (potassium) carbonate, and sodium carbonate]. In contrast, the '450 patent teaches and claims the use of alkali metal carbonates to stabilize ACE inhibitors against cyclization and discoloration. **I agree with Dr. Williams' opinion that the fact that this class of materials does not perform a stabilization function in the amfenac formulations, but does in the claimed ACE inhibitor formulations, would lead one skilled in the art to conclude that these two formulations are simply too different to draw any conclusions regarding what role magnesium oxide might play in stabilizing an ACE inhibitor against cyclization and discoloration [*i.e.*, the context of the invention of the '450 patent].** This is particularly true because the JP references do not contain a saccharide, and the '450 patent recognizes the potential for the saccharide component to interfere with the other components of the formulation. In my opinion, the stabilization mechanisms in the two formulations are probably different. While

amfenac's stability is based on the presence of divalent metals, the stability of the ACE inhibitors disclosed in the '450 patent cannot be based on this, since the claimed stabilizers do not all contain divalent metals. **This indicates to me that magnesium oxide would not have been recognized to be interchangeable with the "alkali or alkaline earth metal carbonate" of the claimed invention by one of ordinary skill in the art on November 11, 1987.** (Gokel Decl. ¶ 27; see also Williams Decl. ¶ 29).

* JP '710 is directed to preparing an intraoral paste containing amfenac and one excipient selected from magnesium oxide, basic magnesium carbonate and calcium carbonate. The other components of the paste are white petroleum jelly, plastibase, carboxymethylcellulose and liquid paraffin. . . . **The fact that magnesium oxide in the presence of a set of components for making a paste may provide a stabilizing function for a nonsteroidal anti-inflammatory [*i.e.*, amfenac] would not lead one of skill in the art to conclude that magnesium oxide in the presence of a different set of components (*i.e.*, ones for making a solid dosage form) would stabilize an ACE inhibitor against cyclization and discoloration [as is required by the "alkali or alkaline earth metal carbonate" element of the '450 patent].** This is particularly true where the claims of the '450 patent require the presence of a saccharide, which, in my opinion, the paste of JP '710 does not contain. The '450 patent also recognizes that the saccharide component could affect the functions of the other components of the formulation. (Williams Decl. 27-28).

* The '919 patent [another of the references relied upon by Paddock] concerns isocarbostyril derivatives, not ACE inhibitors. **In my opinion, the structures of isocarbostyril derivatives and ACE inhibitors are sufficiently different that persons of ordinary skill in the art would not consider methods of stabilizing those compounds to be interchangeable.** (Gokel Decl. ¶ 32; *see also* Williams Decl. ¶ 32).

* GB '271 [British Patent No. 2016271] concerns compositions of Gefarnate. GB' 271 states that Gefarnate is an "oily liquid," and that solid preparations are produced by allowing it to be absorbed in a highly oil-absorptive solid. GB '271 does not disclose Gefarnate as susceptible to cyclization and discoloration, let alone teach the use of any agent to stabilize against these types of degradation. . . . Indeed, **the reference refers to magnesium oxide as "carrier." This suggests that magnesium oxide is not a stabilizing agent against any type of degradation. Thus,**

in my opinion, this reference does not render the use of magnesium oxide to stabilize an ACE inhibitor against cyclization and discoloration, or just cyclization, foreseeable to a person of ordinary skill in the art as of November 11, 1987. (Williams Decl. ¶ 49).[5]

* **Having considered the '450 patent, its prosecution history, including the references before the examiner during prosecution, and the references relied upon by Paddock, it is my opinion that one of ordinary skill in the art on November 11, 1987 would not have recognized magnesium oxide to be interchangeable with an alkali or alkaline earth metal carbonate in the context of the invention of the '450 patent. Nothing I have reviewed in connection with this case has led me to believe that a person of ordinary skill in the art at that time would have known magnesium oxide to be a substitute for an alkali or alkaline earth metal carbonate in the claimed ACE inhibitor formulation.** (Gokel Decl., ¶ 32).

* **In my opinion, as of November 1987, magnesium oxide would not have been recognized by one of ordinary skill in the art as interchangeable with the alkali or alkaline earth metal carbonate element in the claims of the '450 patent. At that time, they were not known substitutes. I reach this opinion based on a consideration of the '450 patent, its specification, its prosecution history, including the art before the Examiner during prosecution, the references identified by Dr. Dash and Paddock, and my knowledge and experience in the pharmaceutical field. To the extent that Paddock and Dr. Dash take a contrary view, I strongly disagree.** (Williams. Decl., ¶ 50).

As the above establishes, far from admitting known interchangeability at the time of amendment, as the patentee did in *Glaxo*, Schwarz Pharma has here supplied abundant evidence disputing that alleged fact. Schwarz Pharma's evidence provides detailed

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[5] The Court states in its opinion that Paddock maintains that this Great Britain patent references magnesium oxide as a "stabilizer." (Opinion at 13). As shown above, Schwarz Pharma's expert states that the patent references magnesium oxide as "carrier." Thus, there is a fundamental disagreement between the parties about what this references discloses with respect to magnesium oxide. For this reason, and those discussed in Section C below, genuinely disputed issues of material fact also exist as to whether magnesium oxide was a known stabilizer against cyclization generally in the art of pharmaceutical formulations at the time of amendment.

scientific explanations as to why, despite the disclosures of Paddock's references, at the time of amendment, a person of ordinary skill in the art would not have recognized magnesium oxide to be interchangeable with an "alkali or alkaline earth metal carbonate" in the claimed invention, given the context of that invention. It is the very type of evidence the Court found absent in *Glaxo*.

On summary judgment, this Court should have credited Schwarz Pharma's above evidence. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986) ("[I]t is clear enough from our recent cases that at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial."); *Id.* at 255 ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.") This Court's failure to do so appears to have arisen from a misreading of *Glaxo*. When this evidence is properly considered, it unquestionably requires denial of Paddock's motion.

Indeed, Dr. Gokel's and Dr. William's scientific explanations as to why, despite the disclosures in Paddock's references, an ordinarily skilled artisan would not have recognized magnesium oxide to be interchangeable with an alkali or alkaline earth metal carbonate, given the context of the claimed invention, are undisputed. Paddock's expert Dr. Dash simply never addressed their scientific points. But, even if he had done so, it would still not entitle Paddock to summary judgment. *See Edwards Systems Technology, Inc. v. Digital Control Systems, Inc.*, 99 Fed. Appx. 911, 921 (Fed. Cir. 2004) (vacating grant of summary judgment of non-infringement were there were dueling experts); *United States v. Ryan*, 2005 WL 1429760, at *10 (W.D. Mo. June 16, 2005) ("The Court

must refrain from weighing the credibility of the competing expert opinions in ruling on this Motion for Summary Judgment."). Simply put, a "battle of the experts" is not amenable to summary judgment.

This is particularly true given that Schwarz Pharma has submitted evidence that raises substantial questions about the credibility of Paddock's expert, Dr. Dash. His opinion that, from the perspective of today, magnesium oxide is, in fact, not interchangeable with an alkali or alkaline earth metal carbonate raises serious questions about how he could credibly opine that a person of skill in the art would have recognized magnesium oxide to be interchangeable with that claim element some 18 years ago, at the time of claim amendment. *See* Gokel Decl. at ¶ 16; Williams Decl. at ¶ 22. By misreading the *Glaxo* case, and thereby reading the recognition-of-interchangeability requirement out of the Federal Circuit's foreseeability standard, this Court missed the significance of this credibility issue to the ultimate resolution of this case. As the Supreme Court has directed district courts repeatedly, credibility determinations are not resolved on summary judgment. *See, e.g., Anderson,* 477 U.S. at 255.[6] For this additional reason, this Court's erred in granting summary judgment.

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[6] This prohibition on weighing credibility applies equally to both cases that are slated for bench trial as well as those scheduled for jury trial. *See Borden, Inc. v. Spoor Behrins Campbell & Young, Inc.*, 828 F. Supp. 216, 218-19 (S.D.N.Y. 1993) ("the standard for granting summary judgment under Rule 56, Fed.R.Civ.P. remains the same whether a jury trial or a bench trial is anticipated"); *see also Tlamka v. Serrell*, 244 F.3d 628, 634 (8th Cir. 2001) ("We may neither weigh evidence nor make credibility determinations at the summary judgment stage.")

C. This Court Erred In Concluding that Magnesium Oxide Is Known in the Prior Art as A Stabilizing Agent

This Court's foreseeability analysis discussed above is premised on the following conclusion:

> The Court finds that an analysis of the entire record and the testimony of the experts, reveals that magnesium oxide was a known stabilizer in the field of pharmaceutical formulation at the time of amendment of the '450 patent.

(Opinion, at 13). Schwarz Pharma submits that this conclusion represents a factual finding that is inappropriate in the context of summary judgment. As the Supreme Court had directed, "[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. Consequently, Schwarz Pharma, the non-moving party "only need[s] to show the existence of a genuine issue of material fact in order to preclude summary judgment." *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1363 (Fed. Cir. 2005). "In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the party opposing the motion, with any doubts resolved in favor of the [non-moving party]." *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274 (Fed. Cir. 1995). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson,* 477 U.S. at 255.

Schwarz Pharma respectfully submits that this Court overlooked these principles in granting Paddock summary judgment. At the hearing on Paddock's summary judgment motion, the Court specifically asked whether different or additional evidence

would be presented at trial. Tr. 34:23-36:1. Schwarz Pharma respectfully submits that this is legally irrelevant. Even if the evidence presented at trial is no different than that presented on summary judgment, the Court's function on summary judgment remains the same: "the judge's function is not himself to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. Yet, as the above quotation shows, this Court did an "analysis of the entire record and the testimony of the experts" to reach factual conclusions regarding the state of the prior art when those facts are genuinely disputed. Indeed, with all due respect, the Court's opinion never discusses whether Schwarz Pharma's evidence raises a genuine issue of fact for trial. This is error.

For example, here, this Court concluded that magnesium oxide was a known stabilizer in the field of pharmaceutical formulations at the time of amendment of the '450 patent. As an initial matter, Schwarz Pharma respectfully submits that the nature of the Court's finding is unclear. The Court described Paddock's references as showing that magnesium oxide was a known stabilizer. (Opinion at 13). But the Court did not identify *any* degradation pathway that magnesium oxide was supposedly known, based on Paddock's references, to stabilize against. The Court failed to do so even though it construed the claims of the '450 patent to require that the "alkali or alkaline earth metal carbonate" stabilize against a particular degradation pathway, cyclization.[7] Thus, the relevant inquiry for foreseeability purposes concerns whether the prior art establishes that

[7] Claim 1 also requires stabilization against discoloration.

magnesium oxide was known in the art of pharmaceutical formulations, at the time of amendment, to stabilize against cyclization with respect to any active pharmaceutical ingredient.

Here, Schwarz Pharma disputed this. Schwarz Pharma submitted the Handbook of Pharmaceutical Excipients. That Handbook describes magnesium oxide as a diluent, not a stabilizer. (Wiesner Ex. 11; *see also* Williams Decl. ¶ 22). This shows that those of skill in the art recognized magnesium oxide to be a diluent. On summary judgment, Schwarz Pharma was entitled to have this evidence believed. *Anderson,* 477 U.S. at 255 ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor."). Moreover, Paddock itself described magnesium oxide as a diluent in its filings with the Food and Drug Administration. (Wiesner Ex. 2). This too supports a reasonable inference that magnesium oxide was not known at the time of amendment to be a stabilizer against cyclization in the art of pharmaceutical formulation with respect to any active pharmaceutical ingredient. By failing to credit this evidence, the Court committed reversible error.

The Court compounded that error when it also failed to credit Schwarz Pharma's evidence that disputed whether Paddock's references would have been understood at the time of amendment by an ordinarily-skilled artisan as showing the use of magnesium oxide as a stabilizer against cyclization. As Schwarz Pharma's technical experts explained, the record before the Court does not contain one single piece of prior art that expressly describes magnesium oxide as a stabilizer against cyclization:

> Paddock does not cite a single reference that expressly discloses the use of magnesium oxide to stabilize an API against cyclization prior to November 11, 1987. **This suggests to me that it was not known to those of ordinary skill in the art at the time that magnesium oxide could stabilize APIs against cyclization.** (Gokel Decl. ¶ 22).
>
> In my opinion, **it is telling that Paddock cannot cite a single reference that explicitly discloses the use of magnesium oxide to stabilize an ACE inhibitor, or any API for that matter, against cyclization. Instead, Paddock relies on hindsight to characterize these references as implicitly disclosing the use of magnesium oxide for that purpose.** In my opinion, a person of ordinary skill in the art of the '450 patent in November of 1987 would not have considered such references relevant to the field of ACE inhibitors or the stability of ACE inhibitors against cyclization and discoloration, or against just cyclization. (Williams Decl. ¶ 36).

Schwarz Pharma submits that a reasonable fact finder can infer from this factual evidence -- which must be credited on summary judgment -- that magnesium oxide was not known by those of skill in the art at the time of amendment to be a stabilizer of any active pharmaceutical ingredient against cyclization. Indeed, Schwarz Pharma submitted evidence that Paddock's contentions to the contrary are the work of hindsight. *See* Williams Decl. ¶ 36 ("Paddock relies on hindsight to characterize these references."); Gokel Decl. ¶25 ("In my opinion, Dr. Dash's opinion regarding the possible degradation mechanisms of amfenac does not speak to what the JP references would have taught a person of ordinary skill in the art on November 11, 1987."). This evidence too should have been credited on summary judgment.

Schwarz Pharma also submits that the Court erred in overlooking basic factual disputes as to how Paddock's references characterize magnesium oxide. As noted above, Paddock contends that British Patent No. 2016271 discloses magnesium oxide as a stabilizer. Schwarz Pharma's experts state that it describes magnesium oxide as a carrier. *See, supra*, footnote 5. Similarly, the parties also dispute whether certain Paddock references even disclose cyclization as degradation pathway or the use of any agent to stabilize against that type of degradation. *Cf., e.g.,* Williams Decl. ¶ 37 (opining that U.S. patent No. 5,045,321 fails to disclose an active pharmaceutical ingredient that is susceptible to cyclization or the use of any agent, let alone magnesium oxide, to stabilize against cyclization) *with* Dash Decl. ¶ 82 (opining that this reference discloses magnesium oxide as a stabilizer but not identifying as a stabilizer of what, or citing any particular portion of the patent); s*ee also* Williams Decl. ¶¶ 38-50 (opining that Paddock's other references fail to show cyclization as a degradation product or the use of any agent, let alone magnesium oxide, to stabilize against cyclization).[8] These factual disputes cannot be resolved on summary judgment.

In sum, at the end of the day, the issue of whether magnesium oxide was known by those of ordinary skill in the art of pharmaceutical formulations to be a stabilizer of an active pharmaceutical ingredient against cyclization, at the time of amendment, is a pure

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[8] Again, with all due respect to the Court, the Court's statement that Paddock's references disclose magnesium oxide as a stabilizer is puzzling given that with respect to numerous references, the references simply disclose formulations that contain magnesium oxide without any evidence that magnesium oxide is stabilizing anything, let alone, stabilizing against cyclization.

question of fact. Schwarz Pharma has submitted evidence that should have been credited on summary judgment showing that magnesium oxide was not known to be such a stabilizer. Paddock's references -- whatever they disclose -- cannot erase Schwarz Pharma's evidence to the contrary. At most, they create a factual dispute that cannot be resolved on summary judgment. This is especially true where Schwarz Pharma disputes Paddock's expert's hindsight-driven attempts to reinterpret Paddock's references as disclosing magnesium oxide as a stabilizer of an active pharmaceutical ingredient against cyclization. The Court erred is resolving all of these factual disputes on summary judgment.

III. CONCLUSION

For the above reasons, there are genuine issues of material fact concerning Paddock's infringement of the '450 patent under the doctrine of equivalents. Accordingly, the Court's prior decision is in error. The Court should correct its mistaken grant of summary judgment, deny Paddock's motion, and vacate its judgment of non-infringement.

Dated: October 26, 2006.

Respectfully Submitted,

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